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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,566	09/10/2003	Christophe Dupont	2756.001	4677

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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,566	DUPONT ET AL.	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4, 6-12, and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-12, and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 sheets, 10 September 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Remarks filed on 1 April 2008 has been acknowledged and duly made of record.

The essence of applicants' arguments are drawn principally to the properness of Examiner's references in the 103(a) rejection. The essential limitation that applicants' purport to be the inventive objective of the current invention is the use of an active substance in a dry form and as individualized or agglomerated particles without any preliminary mix with an excipient to form a film, thereby preventing any alteration of the active substance induced by the excipient.

The references as incorporated in the current 103(a) rejection are all withdrawn upon reconsideration with the exception of Fischer (USPN 4836217).

Fischer sufficiently teaches the inventive objective of claimed invention. The limitations attributed to dermal patches according to claimed invention are generally part of the normal function and therapeutic intent of a dermal patch. The pulverulent form of a bioactive agent or agents contains natural properties directed to electrostatic forces. The claimed invention simply describes a variation of the FINN CHAMBERS patch. In the absence of surprising or unexpected results, the claimed invention is made obvious over Fischer.

The specification discloses the conclusion of an Experiment (page 17), which neither suggests nor supports results which distinguish the inventive objective of claimed invention from that of well-established art. In the case of this current invention, correlative data and cumulative results of various patches including the patch of claimed invention should adequately delineate a representative improvement. However, the specification cites nothing which makes the patch of current invention unobvious. Applicants have cited in the conclusion that the patch of the present

invention proved to be as sensitive as the FINN CHAMBERS method. [Further] [i]n two cases, the results proved to be conflicting, without it being possible to distinguish the two methods. The one of skill would be inclined to deem the patch of current invention as a re-formed FINN CHAMBER dermal patch. The myriad of limitations of the claimed invention drawn to an atopy patch have yielded no distinct results from that of the common well-known brands, whether individualized or agglomerated (particles).

Further, applicants cite a limitation in the Remarks which are neither suggested nor supported in the current claim set:

> The invention thus allows to use the active substance in a dry form and as individualized or agglomerated particles without any preliminary mix with an excipient to form a film, thereby preventing any alteration of the active substance induced by this excipient.
>
> In summary, Fischer fails to teach how to obtain a patch with an active substance in a dry and native form and as individualized or agglomerated particles without use of any film-forming excipient.

This explanation directly drawn to the limitation of **no excipients** is silent within the current claim set. The Fischer reference incorporates in one embodiment of the invention a means of detecting the proper distribution of the active agent via a film-forming carrier. Also Fischer mentions nothing in the whole reference about excipients in some sort of preliminary mix. Still further, applicants purport that this alleged preliminary mix would alter the active substance induced by the excipient. However, this limitation is not deemed to be the inventive objective of the claimed invention. Specifically, the current claim set is silent in view of this particular limitation and alleged objective.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6,8, 10-12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (already incorporated by reference) in view of Antelman, M (WO/2001/049302) and Peck (USPN 4,821,733).

Fischer teaches a novel device and method for carrying out occlusive epicutaneous tests (patch tests). This type of test is employed for detecting contact allergy to some specific substance (allergen) or for testing allergenic and/or irritant properties of a substance. The invention is characterized in that the test substance is incorporated in a **dry film** (abstract only).

According to the instant specification, the expression, "electrostatic support" denotes any support made of a material capable of accumulating electrostatic charges and of conserving them by thus, developing maintaining forces, **in particular by rubbing, heating or ionization, or any other technique** (fourth paragraph, pg. 9).

Fischer, in kind, teaches that there are two important steps in the manufacturing procedure which are of prime importance for the result obtained: (1)

The test allergen has to be distributed uniformly in the film-forming material. (2) The film carrier has to be coated reproducibly with a film of even thickness. If a hydrophilic vehicle is chosen to be employed on a film carrier which is too hydrophobic in character it may turn out to be difficult to uniformly coat the carrier with the vehicle. In such a case the carrier may be treated so as to be made more hydrophilic. Thus, for instance, a polyester film may be treated for a short period of time in an electric field (e.g. corona discharge treatment), or a polyethylene film may be partially oxidized to introduce polar structures (column 5, lines 43-56). The above explanation would be recognized by the skilled artisan as an example of electrostatic support according to the definition disclosed in the instant specification.

Fischer teaches a feature of the patch which determines threshold values for a patient by a design of the patch which imparts a different amount/ unit area of the same antigen. Fischer further goes into detail with another limitation of the function of the patch which provides different allergens each, and/or with the same allergen in different amounts per unit area. By virtue of the varying concentrations and classification of allergen, electrostatic properties would conceivably differ. Thus, Fischer adequately teaches the limitation of claim 12 (col. 6, lines 28-31 and 46-58).

Fischer further teaches the employment of strips as equivalent to other types of patch shapes (see specification, page 17, Conclusion).

Fischer does not teach a method of substantially freeing an active substance of an auxiliary substance when applied topically via dermal patch. Accordingly, the reference to electrostatic properties and forces are not taught expressly be Fischer.

However, Antelman teaches methods in the application of a patch which involves the administration of at least one electron active compound, that has at least two polyvalent cations, at least one of which has a first valence state and at least one of which has a second different valence state, to treat or manage the condition (page 4, 6th paragraph; page 8, 2nd paragraph, last paragraph; page 9, (powerful electrostatic forces).

Additionally, Antelman teaches an embodiment drawn to a composition of said active agent administrated directly in powder form, for treating a wide assortment of skin conditions and diseases (page 12, 6th paragraph; page 14, 8th paragraph).

Antelman, however, does not teach an atopy (sensitization) patch, but does adequately describe the nature of electrostatic forces and properties of bioactive particles in regard to dermal patches which are facilitated by the patch design.

Antelman also does not describe or disclose other specialized features of a dermal patch as disclosed in claims 10 and 11.

However, Peck teaches a transdermal detection system for the detection of a target substance which migrates to the surface of the skin of a subject by diffusion comprises detector means and attachment means. The detector means includes at least one detector chemical contained in solution and capable of chemically reacting with the target substance as the target substance migrates to the skin surface of the subject to produce a detectable signal, and a barrier means for substantially preventing migration of the detector chemical into the skin surface of the

subject. The attachment means maintains the detector means adjacent the surface of the skin of the subject (abstract only).

Peck teaches [that] [t]he detector chemical contained in the detector means is capable of chemically reacting with the target substance as the target substance migrates to the surface of the skin of the subject to produce a detectable signal. The detectable signal which results may be, for example, an optically detectable signal such as a visible color change or an electrically detectable signal such as a pH change, i.e. a change in the hydrogen ion concentration, or other ion concentrations change. Other optically and electrically detectable signals which may result from the chemical reaction of the detector chemical with the target substance will be apparent to one skilled in the art and are included within the scope of the present invention (column 4, lines 1-14).

Claim 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer, Antelman and Peck as applied to claims 1-6, 7,8, 10-12 and 14-17 above, and further in view of Lipper et al. (WO 02/076379 A2).

Lipper et al. teach a medicated tattoo [which]comprises a section of cardstock base paper (70), clear base (50) having an ink design on one side and attached to (70) on the other side by a release base (60) which dissolves when wet to allow detachment of (70); an adhesive layer (20) coated over the ink design on (50) for adhesion to the skin; and a medicament incorporated in the adhesive layer for diffusion into the skin of the wearer. The adhesive layer is formed with one from micropores and microchannels having pre-determined permeability characteristics (abstract only).

Also, Lipper et al. teach [that] the tattoo further comprises a permeable membrane between the drug substance layer and (200) for controlling desorption of the medicament through (20). The tattoo further comprises an indicator dye incorporated into the drug substance layer which migrates with the medicament **to indicate progress or which changes over time to indicate useful life; or a layer incorporated into the drug substance layer and visible in conjugation with the colored design layer to provide a color-changing design as a child incentive to wear** (page 18).

Thus, it would have been prima facie obvious to the one of skill at the time of invention to at once recognize a reasonable expectation of success via the combining and incorporating together the teachings and methods of Fischer, Antelman, Peck, Lipper, and Schoendorfer. The differences between the prior art and the claims at issue are the limitations of claims 2 and 4 which are drawn to common and normal features of most dermal patches, transdermal patches, band-aids, etc. The limitations of claims 2 and 4 are normal functional attributes of a dermal patch.

Considering objective evidence present in the application indicating obviousness or nonobviousness, atopy patches are well-known in the art. Variations and variable constructions of such patches make the claimed invention obvious. The teachings of Fischer principally, disclose art that encompasses the inventive objective of the claimed invention. Antelman discloses the electrostatic

properties of bioactive agents on dermal patches. Peck teaches a colored indicator sensitive to local variations of p H. Lipper teaches the use of a tattoo patch, which is not only medicated but also serves as an indicator dye to monitor the progression of active agent. The references cited above all teach the administration of a dermal patch. The one of skill would be inclined to incorporate these references together because the Fischer reference provides the inventive objective by which the references that follow teach reasonable features to improve therapeutic efficacy. Also, reasonably the one of skill would instantly recognize that the references overlap as far as the device implemented for therapeutic administration. The references complement one another in that particularly the improvements of Peck and Lipper in view of the claimed invention are improvements which reasonably flow with the course of the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617